

cantly lower mean Total scores than controls (54.7 vs. 99.2; $P < 0.0001$), Sleep/energy scores (55.9 vs. 100.0; $P < 0.0001$), and Bother/concern scores (54.0 vs. 98.3; $P < 0.0001$), indicating greater health-related quality of life impairment because of nighttime urination. **CONCLUSIONS:** The Stanford Sleepiness Scale, Epworth Sleepiness Scale, and N-QoL all effectively discriminate between participants with OAB symptoms and those without OAB symptoms.

PMD86

A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS CONDUCTED FOR ASSESSMENT OF GENETIC TESTING TECHNOLOGIES

Assasi N, Schwartz L, Tarride JE, Goeree R, Xie F
McMaster University, Hamilton, ON, Canada

OBJECTIVES: The conventional economic evaluations (EE) methods may be challenging within the context of genetic testing technologies (GTTs), because the main outcome a GTT is information, benefits may occur many years after taking the test, non-medical harms might be associated with GTTs, and GTTs may also provide information about the genetic status of the family members of affected individuals. This study was performed to systematically review the methods used in EEs included in Health Technology Assessments (HTAs) of GTTs. **METHODS:** A systematic search of literature was undertaken to identify HTA reports on GTTs that included EEs in addition to clinical effectiveness results. Studies were reviewed in terms of methods (e.g. type of EE, analytic perspective, cost-effectiveness analysis), and quality (using QHEs instrument). **RESULTS:** Of 342 identified citations, 13 HTAs consisting of 10 model-based and 3 trial-based EEs were included. More than 50% of the included studies had moderate to low quality scores mainly due to not reporting information on basic elements of a standard EE and inadequate management of uncertainty. Cost-effectiveness analysis (CEA) accounted for 62% of included studies. 65% of the studies adopted a third party payer perspective, and 60% used a lifelong time horizon. 75% of CEAs reported intermediate outcomes (e.g. cases-detected). The majority of studies exclusively included technical costs of testing (100%) and therapeutic or preventive interventions (62%). The most frequent variables tested in univariate sensitivity analysis included costs (62%), effects (46%) and transition probabilities (54%). Probabilistic sensitivity analysis was conducted in 31% of studies. **CONCLUSIONS:** We found several methodological challenges in the reviewed EEs, including: identification of a proper analytical perspective, inclusion of wider range of outcomes and costs, allowing for long-term psychological, ethical and social impacts of genetic tests, and sufficient management of uncertainty. These issues should be carefully considered in future EEs of GTTs.

Surgery – Clinical Outcomes Studies

PSU1

SUPRABUBIC TUBE PLACEMENT RELATED BOWEL INJURY: PROPOSED GUIDELINES FOR OPEN PLACEMENT

Ellsworth P¹, Tompkins A¹, Lasser M²

¹Brown University, Providence, RI, USA, ²Brown University, Providence, RI, USA

OBJECTIVES: Suprapubic catheterization (SPT) is a common urologic procedure performed on an elective and urgent basis. Percutaneous approaches have developed in an effort to circumvent the need for general/spinal anesthesia, but are not without risk. Rates of SPT-related bowel injury range from 0.3% to 2.7%. We experienced 4 cases and reviewed the literature to determine identifiable risk factors for bowel injury. **METHODS:** A literature review was performed of all English language articles listed in PubMed and articles reporting percutaneous SPT placement related bowel injury were selected. Included in our review are 4 cases in our institution. Data from articles and our cases was extracted to determine the technique of SPT placement utilized, underlying risk factors, and nature of bowel injury. **RESULTS:** Nineteen papers reported 22 cases of bowel injury as a result of percutaneous SPT placement, 2 of which were excluded for insufficient data. Additionally, the 4 cases at our institution were included in the analysis. Small capacity or thick-walled neurogenic bladders (4/24, 17%), prior abdominal surgery (13/24, 54%), and pelvic radiation (5/24, 21%) were associated with bowel injury during SPT placement. Diagnosis of bowel injury was based on history, physical examination and imaging modalities. Bowel injury had a bimodal presentation, at initial placement (14/24, 58%) and at initial SPT change (10/24, 42%). **CONCLUSIONS:** Based on this review we advocate consideration of open SPT placement in patients with small capacity or thick-walled neurogenic bladders, those in whom the bladder cannot be distended adequately, prior abdominal/pelvic surgery or radiation, ascites. If percutaneous SPT is planned, Trendelenburg positioning and use of ultrasound and/or fluoroscopy at time of SPT placement is supported by the literature.

PSU2

COMPARISON OF SEIZURE AND HYDROCEPHALUS AND OTHER CLINICAL CONDITIONS BEFORE AND AFTER SUBEPENDYMAL GIANT CELL ASTROCYTOMA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX

Sun P¹, Liu Z², Rogerio J², Guo A², Garay C², Kohrman M³

¹Kailo Research Group, Fishers, IN, USA, ²Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, ³University of Chicago, Chicago, IL, USA

OBJECTIVES: To compare the prevalence rates of seizure, hydrocephalus and other clinical conditions before and after a surgical removal of subependymal giant cell astrocytoma (SEGA) in patients with tuberous sclerosis complex (TSC). **METHODS:** A pre-post comparative longitudinal cohort study was conducted based on 3 large US national healthcare claims databases (2000-2009). TSC patients with a first observed SEGA surgery at age 35 or younger and with continuous health insurance coverage 1 year before and 1 year after the surgery were selected. The prevalence rates of seizure, hydrocephalus, and other TSC related clinical conditions, such as vision disorders, coma, speechlessness, headache, stroke or hemiparesis, cognitive

difficulties, muscle weakness, papilloedema, balance disorders, loss of sensation, nausea and vomiting, depression, anxiety, attention deficit disorders, autism, and sleep disorders, were estimated and compared between a period of the last 6 pre-operative months and the first two postoperative periods (the 2nd to 6th postoperative months; 7th to 12th postoperative months). Repeated measures analysis with bootstrapping re-sampling approach was used for the cross-period comparisons.

RESULTS: The mean age of the select patients (N=47) was 11.6 year at their first observed SEGA surgery; the majority of the patients were male (66%). Statistically significant postoperative increases in the prevalence rates of seizure (23~26%, $p < 0.05$), hydrocephalus (21~26%, $p < 0.05$), headache (17~19%, $p < 0.05$), stroke and hemiparesis (6~9%, $p < 0.05$), and autism (9%, $p < 0.05$) were observed.

CONCLUSIONS: This real-world claim data showed an increase in the risk of some clinical conditions including seizure and hydrocephalus after a SEGA surgery in patients with TSC. Further research to explore any possible causal relationship between these risk increases and SEGA surgery through prospective studies or registries is needed.

PSU3

PREVALENCE RATES OF SURGICAL COMPLICATIONS AMONG TUBEROUS SCLEROSIS COMPLEX PATIENTS WITH SURGICAL REMOVAL OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

Sun P¹, Liu Z², Rogerio J², Guo A², Garay C², Kohrman M³

¹Kailo Research Group, Fishers, IN, USA, ²Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, ³University of Chicago, Chicago, IL, USA

OBJECTIVES: To examine the prevalence rates of surgical complications among tuberous sclerosis complex (TSC) patients with surgical removal of subependymal giant cell astrocytoma (SEGA). **METHODS:** Based on 3 US national health care claims databases (2000~2009), a retrospective cohort study was conducted in TSC patients who had a SEGA surgery at age 35 or younger, and were under continuous health insurance coverage 1 year before and 1 year after the surgery. A SEGA surgery was identified by a healthcare claim that simultaneously had a TSC diagnosis code, a benign brain tumor diagnosis code and a procedure code of removing a benign tumor from cerebral ventricle system. The surgical complications examined in the study included surgical procedure complications, nervous system complications, surgical misadventures, postoperative infection, subdural empyemas, and epidural abscess. The prevalence rates of these conditions were estimated for the first postoperative year. **RESULTS:** Approximately 47 TSC patients had at least one SEGA surgery. The mean age of patients at their 1st observed SEGA surgery was 11.6 years. The majority of patients (66%) were male. The prevalence rates of surgical complications in the 1st postoperative year were 34% for surgical procedure complications, 17% for subdural empyemas, 12.8% for nervous system complications, 6% for postoperative infection, 2% for epidural abscess, and 0% for surgical misadventures respectively. **CONCLUSIONS:** In this real-world claim database analysis, we observed that a portion of TSC patients experienced surgical complications within first year after their SEGA surgeries. Further research is needed to better understand the causes of this surgical outcome.

PSU4

POSTOPERATIVE PREVALENCE RATE OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) DIAGNOSIS AND REPEATED SEGA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

Sun P¹, Liu Z², Rogerio J², Guo A², Garay C², Kohrman M³

¹Kailo Research Group, Fishers, IN, USA, ²Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, ³University of Chicago, Chicago, IL, USA

OBJECTIVES: To examine the postoperative prevalence of subependymal giant cell astrocytoma (SEGA) diagnosis and repeated SEGA surgeries among patients with tuberous sclerosis complex (TSC) who had an initial SEGA surgery. **METHODS:** Based on three US national health claims databases (2000~2009), we conducted a retrospective cohort study with TSC patients who had a first observed SEGA surgery at age 35 or younger and were under continuous health insurance coverage 1 year before and 1 year after their 1st SEGA surgery. A SEGA surgery was defined as having 1) a TSC diagnosis code, 2) a benign brain tumor diagnosis code, and 3) a procedure code for removing a benign tumor from cerebral ventricle system. A SEGA diagnosis is defined as 1) and 2). The prevalence rates of postoperative SEGA diagnosis and repeated SEGA surgery were estimated for a period from the 3rd through 6th postoperative month and a period from the 7th through 12th postoperative month respectively. **RESULTS:** The select patients (N=47) had mean age of 11.6 years (at the 1st SEGA surgery) with 66% males. After the 1st observed SEGA surgery, postoperative prevalence rates of SEGA diagnosis was 34% in the period from the 3rd to 6th postoperative month and 26% in the period from the 7th to 12th postoperative month. About 4~9% patients had a repeated SEGA surgery in their 1st postoperative year. **CONCLUSIONS:** In the real-world setting, TSC patients with SEGA surgery may experience repeated SEGA surgeries or/and still have SEGA diagnoses within the first postoperative year. Further research on the effectiveness of SEGA surgery via prospective studies or registries is needed to improve care in TSC patients with SEGA.

PSU5

RISK OF ARTHRITIS AS A PREDICTOR FOR THE MISDIAGNOSIS OF CHONDROLYSIS: AN INTERNATIONAL ANALYSIS OF CLINICAL OUTCOMES

Smith JC¹, Provencher MT², Solomon DJ³, Navaia M⁴

¹Advance Health Solutions, La Jolla, CA, USA, ²Naval Medical Center San Diego, San Diego, CA, USA, ³Marin Orthopedics and Sports Medicine, Novato, CA, USA, ⁴Advance Health Solutions, LLC, La Jolla, CA, USA